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PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

THOMAS LAUER,  
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
G.D. SEARLE LLC and MONSANTO  
COMPANY,

Defendants.

) MDL Docket No. 1699  
)  
) CASE NO. 3:08-cv--02854-CRB  
)  
) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**  
)  
) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as  
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company ) ("Pharmacia") and  
3 G.D. Searle LLC ("Searle") (collectively "Defendants") and file this Answer to Plaintiff's  
4 Complaint ("Complaint"), and would respectfully show the Court as follows:

5 I.

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or  
8 used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted  
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the specific  
10 time periods in which Plaintiff was prescribed and used Bextra®.

11 II.

12 **ORIGINAL ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants are without knowledge or information sufficient to form a belief as to  
15 the truth of the allegations regarding Plaintiff's citizenship, and, therefore, deny the same.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 2. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
18 business in New York, and that it is registered to do business in the State of Minnesota.  
19 Defendants admit that Pfizer may be served through its registered agent. Defendants admit that  
20 Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and  
21 Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time,  
22 Pfizer marketed and co-promoted Bextra® in the United States, including Minnesota, to be  
23 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
24 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding  
25 "predecessors in interest" are vague and ambiguous. Defendants are therefore without  
26 knowledge or information sufficient to form a belief as to the truth of such allegations, and,  
27 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
28 Complaint.

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1           3. Defendants admit that Searle is a Delaware limited liability company with its  
2 principal place of business in Illinois, and that it is registered to do business in the State of  
3 Minnesota. Defendants admit that Searle may be served through its registered agent.  
4 Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in  
5 April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during  
6 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,  
7 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by  
8 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
9 approval by the FDA. Defendants deny the remaining allegations in this paragraph of the  
10 Complaint.

11           4. Defendants admit that Pharmacia is a Delaware corporation with its principal  
12 place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and  
13 that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
14 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
15 Bextra® in the United States to be prescribed by healthcare providers who are by law authorized  
16 to prescribe drugs in accordance with their approval by the FDA. Defendants state that  
17 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants  
18 are therefore without knowledge or information sufficient to form a belief as to the truth of such  
19 allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this  
20 paragraph of the Complaint.

21           5. Defendants admit that in 1933 an entity known as Monsanto Company ("1933  
22 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of  
23 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to  
24 Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was  
25 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed  
26 its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the  
27 agricultural business and does not and has not ever manufactured, marketed, sold, or distributed  
28 Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia.

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1 As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed  
2 Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter.  
3 Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state  
4 that the response to this paragraph of the Complaint regarding Monsanto is incorporated by  
5 reference into Defendants' responses to each and every paragraph of the Complaint referring to  
6 Monsanto and/or Defendants.

7 6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
8 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
9 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
10 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
11 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
12 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
13 drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired  
14 Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became  
15 subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the  
16 Complaint.

17 7. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
18 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
19 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
20 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
21 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
22 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
23 drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is  
24 safe and effective when used in accordance with its FDA-approved prescribing information.  
25 Defendants state that the potential effects of Bextra® were and are adequately described in its  
26 FDA-approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
28 remaining allegations in this paragraph of the Complaint.

8. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

## **Response to Factual Allegations**

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1 state that the potential effects of Bextra® were and are adequately described in its FDA-  
2 approved prescribing information, which was at all times adequate and comported with  
3 applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra®  
4 caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the  
5 Complaint.

6 14. Defendants are without knowledge or information sufficient to form a belief as to  
7 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
8 Bextra®, and, therefore, deny the same. Defendants state that, in the ordinary case, Bextra® was  
9 expected to reach users and consumers without substantial change from the time of sale.  
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 15. Defendants are without knowledge or information sufficient to form a belief as to  
12 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
13 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Bextra® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as  
20 non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that the allegations in this  
21 paragraph of the Complaint regarding aspirin, naproxen and ibuprofen are not directed toward  
22 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
23 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
24 paragraph of the Complaint regarding aspirin, naproxen and ibuprofen. Defendants therefore  
25 lack knowledge or information sufficient to form a belief as to the truth of such allegations, and,  
26 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
27 Complaint.

28 17. The allegations in this paragraph of the Complaint are not directed toward

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1 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
2 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
3 paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to  
4 form a belief as to the truth of such allegations, and, therefore, deny the same.

5 18. The allegations in this paragraph of the Complaint are not directed toward  
6 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
7 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
8 paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to  
9 form a belief as to the truth of such allegations, and, therefore, deny the same.

10 19. The allegations in this paragraph of the Complaint are not directed toward  
11 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
12 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
13 paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to  
14 form a belief as to the truth of such allegations, and, therefore, deny the same.

15 20. The allegations in this paragraph of the Complaint are not directed toward  
16 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
17 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
18 paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to  
19 form a belief as to the truth of such allegations, and, therefore, deny the same.

20 21. Plaintiff fails to provide the proper context for the allegations in this paragraph of  
21 the Complaint. Defendants lack knowledge or information sufficient to form a belief as to the  
22 truth of such allegations, and, therefore, deny the same.

23 22. Defendants state that Plaintiff's allegations regarding "predecessors in interest"  
24 are vague and ambiguous. Defendants are therefore without knowledge or information to form a  
25 belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any  
26 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 23. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless,  
28 Defendants admit that Celebrex® was launched in the United States in February 1999.



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1 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
2 FDA-approved prescribing information. Defendants admit that, during certain periods of time,  
3 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed  
4 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
5 approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was  
6 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
7 distributed Celebrex® in the United States to be prescribed by healthcare providers who are by  
8 law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations  
9 in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward  
10 Defendants, and, therefore, no response is required. To the extent a response is deemed required,  
11 Defendants state that Plaintiff fails to provide the proper context for the allegations in this  
12 paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack knowledge  
13 or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
14 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 24. Defendants admit that the New Drug Application for Bextra® was filed with the  
16 FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the  
17 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis  
18 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants  
19 state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.  
20 Defendants are therefore without knowledge or information to form a belief as to the truth of  
21 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in  
22 this paragraph of the Complaint.

23 25. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.  
24 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is  
25 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid  
26 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining  
27 allegations in this paragraph of the Complaint.

28 26. Defendants admit, as indicated in the package insert approved by the FDA, that



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1 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
2 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the  
3 remaining allegations in this paragraph of the Complaint.

4 27. Defendants admit, as indicated in the package insert approved by the FDA, that  
5 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult  
6 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that  
7 Bextra® was and is safe and effective when used in accordance with its FDA-approved  
8 prescribing information. Defendants state that the potential effects of Bextra® were and are  
9 adequately described in its FDA-approved prescribing information, which at all times was  
10 adequate and comported with applicable standards of care and law. Defendants deny the  
11 remaining allegations in this paragraph of the Complaint.

12 28. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
13 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
14 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
15 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
16 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
17 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
18 drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations  
19 regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without  
20 knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny  
21 the same. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information, which  
24 at all times was adequate and comported with applicable standards of care and law. Defendants  
25 deny any wrongful conduct and deny the remaining allegations in this paragraph of the  
26 Complaint.

27 29. Defendants state that the referenced article speaks for itself and respectfully refer  
28 the Court to the article for its actual language and text. Any attempt to characterize the article is

1 denied. Defendants state that Bextra® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
3 this paragraph of the Complaint.

4 30. The allegations in this paragraph of the Complaint are not directed towards  
5 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,  
6 Defendants state that the referenced article speaks for itself and respectfully refer the Court to the  
7 article for its actual language and text. Any attempt to characterize the article is denied.  
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 31. Defendants admit that the New Drug Application for Bextra® was filed with the  
10 FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on  
11 November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in  
12 this paragraph of the Complaint.

13 32. Defendants state that Bextra® was and is safe and effective when used in  
14 accordance with its FDA-approved prescribing information. Defendants state that the potential  
15 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
16 information, which at all times was adequate and comported with applicable standards of care  
17 and law. Defendants deny the allegations in this paragraph of the Complaint.

18 33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself  
19 and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to  
20 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this  
21 paragraph of the Complaint.

22 34. Defendants state that the referenced article speaks for itself and respectfully refer  
23 the Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 35. Plaintiff fails to provide the proper context for the allegations concerning the  
26 “post-drug approval meta-analysis study” in this paragraph of the Complaint. Defendants are  
27 without sufficient information to confirm or deny such allegations, and, therefore, deny the same.  
28 Defendants state that the referenced study speaks for itself and respectfully refer the Court to the

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1 study for its actual language and text. Any attempt to characterize the study is denied.

2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 36. The allegations in this paragraph of the Complaint are not directed towards  
4 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,  
5 Defendants state that the referenced article speaks for itself and respectfully refer the Court to the  
6 article for its actual language and text. Any attempt to characterize the article is denied.  
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 37. The allegations in this paragraph of the Complaint are not directed towards  
9 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,  
10 Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety  
11 and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants  
12 state that the referenced testimony speaks for itself and respectfully refer the Court to the  
13 testimony for its actual language and text. Any attempt to characterize the testimony is denied.  
14 Defendants deny the remaining allegations in this paragraph of the Complaint.

15 38. Defendants state that Bextra® was and is safe and effective when used in  
16 accordance with its FDA-approved prescribing information. Defendants state that the potential  
17 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
18 information, which at all times was adequate and comported with applicable standards of care  
19 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
20 paragraph of the Complaint.

21 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for  
22 itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual  
23 language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 40. Defendants state that the referenced Alert for Healthcare Professionals speaks for  
26 itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual  
27 language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1           41. Defendants state that Bextra® was and is safe and effective when used in  
2 accordance with its FDA-approved prescribing information. Defendants deny the allegations in  
3 this paragraph of the Complaint.

4           42. Defendants state that the referenced article speaks for itself and respectfully refer  
5 the Court to the article for its actual language and text. Any attempt to characterize the article is  
6 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8           43. The allegations in this paragraph of the Complaint are not directed towards  
9 Defendants, and, therefore, no response is necessary. Should a response be deemed necessary,  
10 Defendants state that the referenced article speaks for itself and respectfully refer the Court to the  
11 article for its actual language and text. Any attempt to characterize the article is denied.  
12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13           44. Defendants state that Bextra® was and is safe and effective when used in  
14 accordance with its FDA-approved prescribing information. Defendants state that the potential  
15 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
16 information, which was at all times adequate and comported with applicable standards of care  
17 and law. Defendants deny the allegations in this paragraph of the Complaint.

18           45. Defendants state that Bextra® was and is safe and effective when used in  
19 accordance with its FDA-approved prescribing information. Defendants state that the potential  
20 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
21 information, which was at all times adequate and comported with applicable standards of care  
22 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the  
23 remaining allegations in this paragraph of the Complaint.

24           46. Defendants state that Bextra® was and is safe and effective when used in  
25 accordance with its FDA-approved prescribing information. Defendants state that the potential  
26 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
27 information, which was at all times adequate and comported with applicable standards of care  
28 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 47. Defendants deny the allegations in this paragraph of the Complaint.

3 48. Defendants are without knowledge or information sufficient to form a belief as to  
4 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
5 Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time,  
6 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed  
7 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
8 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was  
9 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
10 distributed Bextra® in the United States to be prescribed by healthcare providers who are by law  
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
12 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
13 prescribing information. Defendants state that the potential effects of Bextra® were and are  
14 adequately described in its FDA-approved prescribing information, which was at all times  
15 adequate and comported with applicable standards of care and law. Defendants deny any  
16 wrongful conduct and deny the allegations in this paragraph of the Complaint.

17 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
18 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
19 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
20 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
21 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
22 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
23 drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is  
24 safe and effective when used in accordance with its FDA-approved prescribing information.  
25 Defendants state that the potential effects of Bextra® were and are adequately described in its  
26 FDA-approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny the remaining allegations in this  
28 paragraph of the Complaint.

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1           50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
2 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
3 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
4 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
5 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
6 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
7 drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the  
8 package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs  
9 and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of  
10 primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used  
11 in accordance with its FDA-approved prescribing information. Defendants state that the  
12 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing  
13 information, which was at all times adequate and comported with applicable standards of care  
14 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
15 paragraph of the Complaint.

16           51. Defendants state that Bextra® was and is safe and effective when used in  
17 accordance with its FDA-approved prescribing information. Defendants state that the potential  
18 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
19 information, which at all times was adequate and comported with applicable standards of care  
20 and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are  
21 vague and ambiguous. Defendants are therefore without knowledge or information to form a  
22 belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any  
23 wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of  
24 the Complaint.

25           52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
26 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
27 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
28 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged

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1 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
2 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
3 drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is  
4 safe and effective when used in accordance with its FDA-approved prescribing information.  
5 Defendants state that the potential effects of Bextra® were and are adequately described in its  
6 FDA-approved prescribing information, which was at all times adequate and comported with  
7 applicable standards of care and law. Defendants deny the remaining allegations in this  
8 paragraph of the Complaint.

9 53. Defendants state that Bextra® was and is safe and effective when used in  
10 accordance with its FDA-approved prescribing information. Defendants state that the potential  
11 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
12 information, which at all times was adequate and comported with applicable standards of care  
13 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 54. Defendants state that Bextra® was and is safe and effective when used in  
15 accordance with its FDA-approved prescribing information. Defendants state that the potential  
16 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
17 information, which was at all times adequate and comported with applicable standards of care  
18 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
19 paragraph of the Complaint.

20 55. Defendants state that Bextra® was and is safe and effective when used in  
21 accordance with its FDA-approved prescribing information. Defendants state that the potential  
22 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
23 information, which was at all times adequate and comported with applicable standards of care  
24 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
25 paragraph of the Complaint.

26 56. Defendants deny the allegations in this paragraph of the Complaint.

27 57. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S.  
28 market as of April 7, 2005. Defendants state that Bextra® was and is safe and effective when



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1 used in accordance with its FDA-approved prescribing information. Defendants deny any  
2 wrongful conduct and deny the remaining allegations contained in this paragraph of the  
3 Complaint.

4 58. Defendants state that Bextra® was and is safe and effective when used in  
5 accordance with its FDA-approved prescribing information. Defendants state that the potential  
6 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
7 information, which was at all times adequate and comported with applicable standards of care  
8 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the  
9 remaining allegations in this paragraph of the Complaint.

10 59. Defendants state that Bextra® was and is safe and effective when used in  
11 accordance with its FDA-approved prescribing information. Defendants state that the potential  
12 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
13 information, which was at all times adequate and comported with applicable standards of care  
14 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
15 paragraph of the Complaint.

16 60. Defendants deny any wrongful conduct and deny the remaining allegations in this  
17 paragraph of the Complaint.

18 61. Defendants are without knowledge or information sufficient to form a belief as to  
19 the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff  
20 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
21 effective when used in accordance with its FDA-approved prescribing information. Defendants  
22 state that the potential effects of Bextra® were and are adequately described in its FDA-  
23 approved prescribing information, which was at all times adequate and comported with  
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
25 remaining allegations in this paragraph of the Complaint.

26 62. Defendants are without knowledge or information sufficient to form a belief as to  
27 the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff  
28 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants  
2 state that the potential effects of Bextra® were and are adequately described in its FDA-  
3 approved prescribing information, which was at all times adequate and comported with  
4 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
5 remaining allegations in this paragraph of the Complaint.

6 63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
7 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
8 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
9 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
10 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
11 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
12 drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the  
13 package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs  
14 and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of  
15 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining  
16 allegations in this paragraph of the Complaint.

17 64. Defendants are without knowledge or information sufficient to form a belief as to  
18 the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff  
19 used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
20 effective when used in accordance with its FDA-approved prescribing information. Defendants  
21 state that the potential effects of Bextra® were and are adequately described in its FDA-  
22 approved prescribing information, which was at all times adequate and comported with  
23 applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra®  
24 is unreasonably dangerous, and deny the remaining allegations in this paragraph of the  
25 Complaint.

26 65. Defendants state that Bextra® was and is safe and effective when used in  
27 accordance with its FDA-approved prescribing information. Defendants state that the potential  
28 effects of Bextra® were and are adequately described in its FDA-approved prescribing

1 information, which was at all times adequate and comported with applicable standards of care  
2 and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are  
3 vague and ambiguous. Defendants are therefore without knowledge or information to form a  
4 belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any  
5 wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or  
6 damages, and deny the remaining allegations in this paragraph of the Complaint.

7 **Response to First Cause of Action: Negligence**

8 66. Defendants incorporate by reference their responses to each paragraph of  
9 Plaintiff's Complaint as if fully set forth herein.

10 67. Defendants state that this paragraph of the Complaint contains legal contentions  
11 to which no response is deemed required. To the extent a response is deemed required,  
12 Defendants admit that they had duties as are imposed by law but deny having breached such  
13 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
14 with its FDA-approved prescribing information. Defendants state that the potential effects of  
15 Bextra® were and are adequately described in its FDA-approved prescribing information, which  
16 was at all times adequate and comported with applicable standards of care and law. Defendants  
17 deny the remaining allegations in this paragraph of the Complaint.

18 68. Defendants state that this paragraph of the Complaint contains legal contentions  
19 to which no response is deemed required. To the extent a response is deemed required,  
20 Defendants admit that they had duties as are imposed by law but deny having breached such  
21 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Bextra® were and are adequately described in its FDA-approved prescribing information, which  
24 was at all times adequate and comported with applicable standards of care and law. Defendants  
25 deny the remaining allegations in this paragraph of the Complaint.

26 69. Defendants state that Bextra® was and is safe and effective when used in  
27 accordance with its FDA-approved prescribing information. Defendants state that the potential  
28 effects of Bextra® were and are adequately described in its FDA-approved prescribing

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1 information, which was at all times adequate and comported with applicable standards of care  
2 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
3 paragraph of the Complaint, including all subparts.

4 70. Defendants are without knowledge or information sufficient to form a belief as to  
5 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
6 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
7 effective when used in accordance with its FDA-approved prescribing information. Defendants  
8 state that the potential effects of Bextra® were and are adequately described in its FDA-  
9 approved prescribing information, which was at all times adequate and comported with  
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra®  
11 is unreasonably dangerous, and deny the remaining allegations in this paragraph of the  
12 Complaint.

13 71. Defendants state that Bextra® was and is safe and effective when used in  
14 accordance with its FDA-approved prescribing information. Defendants state that the potential  
15 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
16 information, which was at all times adequate and comported with applicable standards of care  
17 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
18 paragraph of the Complaint.

19 72. Defendants are without knowledge or information sufficient to form a belief as to  
20 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
21 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Bextra® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
26 remaining allegations in this paragraph of the Complaint.

27 73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
28 or damages, and deny the remaining allegations in this paragraph of the Complaint.

1           74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
2 or damages and deny the remaining allegations in this paragraph of the Complaint.

3           Answering the unnumbered paragraph following Paragraph 74 of the Complaint,  
4 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages,  
5 and deny the remaining allegations in this paragraph of the Complaint.

6                           **Response to Second Cause of Action: Strict Liability**

7           75. Defendants incorporate by reference their responses to each paragraph of  
8 Plaintiff's Complaint as if fully set forth herein.

9           76. Defendants are without knowledge or information sufficient to form a belief as to  
10 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time,  
12 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed  
13 by healthcare providers who are by law authorized to prescribe drugs in accordance with their  
14 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was  
15 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
16 distributed Bextra® in the United States to be prescribed by healthcare providers who are by law  
17 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
18 that Bextra® was expected to reach consumers without substantial change in the condition from  
19 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

20           77. Defendants state that Bextra® was and is safe and effective when used in  
21 accordance with its FDA-approved prescribing information. Defendants state that the potential  
22 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
23 information, which was at all times adequate and comported with applicable standards of care  
24 and law. Defendants deny the allegations in this paragraph of the Complaint.

25           78. Defendants state that Bextra® was and is safe and effective when used in  
26 accordance with its FDA-approved prescribing information. Defendants state that the potential  
27 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
28 information, which was at all times adequate and comported with applicable standards of care

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1 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or  
2 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

3 79. Defendants state that Bextra® was and is safe and effective when used in  
4 accordance with its FDA-approved prescribing information. Defendants state that the potential  
5 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
6 information, which was at all times adequate and comported with applicable standards of care  
7 and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous,  
8 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

9 80. Defendants are without knowledge or information sufficient to form a belief as to  
10 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Bextra® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra®  
16 is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining  
17 allegations in this paragraph of the Complaint.

18 81. Defendants state that Bextra® was and is safe and effective when used in  
19 accordance with its FDA-approved prescribing information. Defendants state that the potential  
20 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
21 information, which was at all times adequate and comported with applicable standards of care  
22 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the  
23 remaining allegations in this paragraph of the Complaint.

24 82. Defendants are without knowledge or information sufficient to form a belief as to  
25 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
26 Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time,  
27 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed  
28 by healthcare providers who are by law authorized to prescribe drugs in accordance with their

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1 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was  
2 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and  
3 distributed Bextra® in the United States to be prescribed by healthcare providers who are by law  
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
5 that Bextra® was and is safe and effective when used in accordance with its FDA-approved  
6 prescribing information. Defendants state that the potential effects of Bextra® were and are  
7 adequately described in its FDA-approved prescribing information, which was at all times  
8 adequate and comported with applicable standards of care and law. Defendants deny any  
9 wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or  
10 damages, and deny the remaining allegations in this paragraph of the Complaint.

11 83. Defendants state that Bextra® was and is safe and effective when used in  
12 accordance with its FDA-approved prescribing information. Defendants state that the potential  
13 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
14 information, which was at all times adequate and comported with applicable standards of care  
15 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
16 paragraph of the Complaint.

17 84. Defendants are without knowledge or information sufficient to form a belief as to  
18 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
19 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
20 effective when used in accordance with its FDA-approved prescribing information. Defendants  
21 state that the potential effects of Bextra® were and are adequately described in its FDA-  
22 approved prescribing information, which was at all times adequate and comported with  
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
24 remaining allegations in this paragraph of the Complaint.

25 85. Defendants state that Bextra® was and is safe and effective when used in  
26 accordance with its FDA-approved prescribing information. Defendants deny any wrongful  
27 conduct and deny the remaining allegations in this paragraph of the Complaint.

28 86. Defendants state that Bextra® was and is safe and effective when used in



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1 accordance with its FDA-approved prescribing information. Defendants state that the potential  
2 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
3 information, which was at all times adequate and comported with applicable standards of care  
4 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the  
5 remaining allegations in this paragraph of the Complaint.

6 87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
7 or damages, and deny the remaining allegations in this paragraph of the Complaint.

8 88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
9 or damages, and deny the remaining allegations in this paragraph of the Complaint.

10 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
11 or damages, and deny the remaining allegations in this paragraph of the Complaint.

12 **Response to Third Cause of Action: Breach of Express Warranty**

13 90. Defendants incorporate by reference their responses to each paragraph of  
14 Plaintiff's Complaint as if fully set forth herein.

15 91. Defendants are without knowledge or information sufficient to form a belief as to  
16 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
17 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Bextra® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants admit that they provided FDA-approved  
22 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this  
23 paragraph of the Complaint.

24 92. Defendants are without knowledge or information sufficient to form a belief as to  
25 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
26 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Bextra® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants admit that they provided FDA-approved  
3 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this  
4 paragraph of the Complaint, including all subparts.

5 93. Defendants deny the allegations in this paragraph of the Complaint.

6 94. Defendants state that Bextra® was and is safe and effective when used in  
7 accordance with its FDA-approved prescribing information. Defendants state that the potential  
8 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
9 information, which was at all times adequate and comported with applicable standards of care  
10 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 95. Defendants state that Bextra® was and is safe and effective when used in  
12 accordance with its FDA-approved prescribing information. Defendants state that the potential  
13 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
14 information, which was at all times adequate and comported with applicable standards of care  
15 and law. Defendants deny any wrongful conduct the remaining allegations in this paragraph of  
16 the Complaint.

17 96. Defendants are without knowledge or information sufficient to form a belief as to  
18 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
19 Bextra®, and, therefore, deny the same. Defendants admit that they provided FDA-approved  
20 prescribing information regarding Bextra®. Defendants deny the remaining allegations in this  
21 paragraph of the Complaint.

22 97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
23 or damages, and deny the remaining allegations in this paragraph of the Complaint.

24 98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
25 or damages, and deny the remaining allegations in this paragraph of the Complaint.

26 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
27 or damages, and deny the remaining allegations in this paragraph of the Complaint.

28 **Response to Fourth Cause of Action: Breach of Implied Warranty**

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1           100. Defendants incorporate by reference their responses to each paragraph of  
2 Plaintiff's Complaint as if fully set forth herein.

3           101. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
4 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
5 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
6 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
7 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
8 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
9 drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations  
10 in this paragraph of the Complaint.

11           102. Defendants admit that they provided FDA-approved prescribing information  
12 regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the  
13 Complaint.

14           103. Defendants state that Bextra® was and is safe and effective when used in  
15 accordance with its FDA-approved prescribing information. Defendants deny any wrongful  
16 conduct and deny the remaining allegations in this paragraph of the Complaint.

17           104. Defendants state that Bextra® was and is safe and effective when used in  
18 accordance with its FDA-approved prescribing information. Defendants state that the potential  
19 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
20 information, which was at all times adequate and comported with applicable standards of care  
21 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
22 paragraph of the Complaint.

23           105. Defendants are without knowledge or information sufficient to form a belief as to  
24 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
25 Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package insert  
26 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms  
27 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary  
28 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1           106. Defendants state that this paragraph of the Complaint contains legal contentions  
2 to which no response is deemed required. To the extent a response is deemed required,  
3 Defendants are without knowledge or information sufficient to form a belief as to the truth of the  
4 allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and,  
5 therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used  
6 in accordance with its FDA-approved prescribing information. Defendants state that the  
7 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing  
8 information, which was at all times adequate and comported with applicable standards of care  
9 and law. Defendants admit that they provided FDA-approved prescribing information regarding  
10 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

11           107. Defendants are without knowledge or information sufficient to form a belief as to  
12 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
13 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was expected to reach  
14 consumers without substantial change in the condition from the time of sale. Defendants deny  
15 the remaining allegations in this paragraph of the Complaint.

16           108. Defendants are without knowledge or information sufficient to form a belief as to  
17 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
18 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
19 effective when used in accordance with its FDA-approved prescribing information. Defendants  
20 state that the potential effects of Bextra® were and are adequately described in its FDA-  
21 approved prescribing information, which was at all times adequate and comported with  
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
23 remaining allegations in this paragraph of the Complaint.

24           109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
25 or damages, and deny the remaining allegations in this paragraph of the Complaint.

26           110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
27 or damages, and deny the remaining allegations in this paragraph of the Complaint.

28           111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury

1 or damages, and deny the remaining allegations in this paragraph of the Complaint.

2 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

3 112. Defendants incorporate by reference their responses to each paragraph of  
4 Plaintiff's Complaint as if fully set forth herein.

5 113. Defendants state that this paragraph of the Complaint contains legal contentions  
6 to which no response is deemed required. To the extent a response is deemed required,  
7 Defendants admit that they had duties as are imposed by law but deny having breached such  
8 duties. Defendants state that Bextra® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Bextra® were and are adequately described in its FDA-approved prescribing information, which  
11 was at all times adequate and comported with applicable standards of care and law. Defendants  
12 deny the remaining allegations in this paragraph of the Complaint.

13 114. Defendants state that Bextra® was and is safe and effective when used in  
14 accordance with its FDA-approved prescribing information. Defendants state that the potential  
15 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
16 information, which was at all times adequate and comported with applicable standards of care  
17 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
18 paragraph of the Complaint, including all subparts.

19 115. Defendants state that Bextra® was and is safe and effective when used in  
20 accordance with its FDA-approved prescribing information. Defendants state that the potential  
21 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
22 information, which was at all times adequate and comported with applicable standards of care  
23 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
24 paragraph of the Complaint.

25 116. Defendants state that Bextra® was and is safe and effective when used in  
26 accordance with its FDA-approved prescribing information. Defendants state that the potential  
27 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
28 information, which was at all times adequate and comported with applicable standards of care

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1 and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or  
2 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

3 117. Defendants state that Bextra® was and is safe and effective when used in  
4 accordance with its FDA-approved prescribing information. Defendants state that the potential  
5 effects of Bextra® were and are adequately described in its FDA-approved prescribing  
6 information, which was at all times adequate and comported with applicable standards of care  
7 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 118. Defendants deny any wrongful conduct and deny the remaining allegations in this  
10 paragraph of the Complaint.

11 119. Defendants are without knowledge or information sufficient to form a belief as to  
12 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
13 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
14 remaining allegations in this paragraph of the Complaint.

15 120. Defendants are without knowledge or information sufficient to form a belief as to  
16 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
17 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 121. Defendants are without knowledge or information sufficient to form a belief as to  
20 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
21 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
22 effective when used in accordance with its FDA-approved prescribing information. Defendants  
23 state that the potential effects of Bextra® were and are adequately described in its FDA-  
24 approved prescribing information, which was at all times adequate and comported with  
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
26 remaining allegations in this paragraph of the Complaint.

27 122. Defendants deny any wrongful conduct and deny the remaining allegations in this  
28 paragraph of the Complaint.

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1           123. Defendants are without knowledge or information sufficient to form a belief as to  
2 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
3 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and  
4 effective when used in accordance with its FDA-approved prescribing information. Defendants  
5 state that the potential effects of Bextra® were and are adequately described in its FDA-  
6 approved prescribing information, which was at all times adequate and comported with  
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
8 remaining allegations in this paragraph of the Complaint.

9           124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
10 or damages, and deny the remaining allegations in this paragraph of the Complaint.

11           125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
12 or damages, and deny the remaining allegations in this paragraph of the Complaint.

13           126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury  
14 or damages, and deny the remaining allegations in this paragraph of the Complaint.

15                   **Response to Sixth Cause of Action: Unjust Enrichment**

16           127. Defendants incorporate by reference their responses to each paragraph of  
17 Plaintiff's Complaint as if fully set forth herein.

18           128. Defendants admit that, during certain periods of time, Pfizer and Pharmacia  
19 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers  
20 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
21 Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged  
22 for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the  
23 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
24 drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations  
25 in this paragraph of the Complaint.

26           129. Defendants are without knowledge or information sufficient to form a belief as to  
27 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
28 Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this



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paragraph of the Complaint.

130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

### **Response to Prayer for Relief**

Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,” Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

### **III.**

### **GENERAL DENIAL**

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

### **IV.**

### **AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to

1 claims asserted by Plaintiff to the extent that such defenses are supported by information  
2 developed through discovery or evidence at trial. Defendants affirmatively show that:

3 **First Defense**

4 1. The Complaint fails to state a claim upon which relief can be granted.

5 **Second Defense**

6 2. Bextra® is a prescription medical product. The federal government has  
7 preempted the field of law applicable to the labeling and warning of prescription medical  
8 products. Defendants' labeling and warning of Bextra® was at all times in compliance with  
9 applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a  
10 claim upon which relief can be granted; such claims, if allowed, would conflict with applicable  
11 federal law and violate the Supremacy Clause of the United States Constitution.

12 **Third Defense**

13 3. At all relevant times, Defendants provided proper warnings, information and  
14 instructions for the drug in accordance with generally recognized and prevailing standards in  
15 existence at the time.

16 **Fourth Defense**

17 4. At all relevant times, Defendants' warnings and instructions with respect to the  
18 use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of  
19 knowledge at the time the drug was manufactured, marketed and distributed.

20 **Fifth Defense**

21 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the  
22 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

23 **Sixth Defense**

24 6. Plaintiff's action is barred by the statute of repose.

25 **Seventh Defense**

26 7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in  
27 the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's  
28 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory

1 negligence and by the failure to mitigate damages.

2 **Eighth Defense**

3 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts  
4 or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the  
5 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not  
6 liable in any way.

7 **Ninth Defense**

8 9. The acts and/or omissions of unrelated third parties as alleged constituted  
9 independent, intervening causes for which Defendants cannot be liable.

10 **Tenth Defense**

11 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but  
12 were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or  
13 act of God.

14 **Eleventh Defense**

15 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

16 **Twelfth Defense**

17 12. A manufacturer has no duty to warn patients or the general public of any risk,  
18 contraindication, or adverse effect associated with the use of a prescription medical product.  
19 Rather, the law requires that all such warnings and appropriate information be given to the  
20 prescribing physician and the medical profession, which act as a “learned intermediary” in  
21 determining the use of the product. Bextra® is a prescription medical product, available only on  
22 the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating  
23 and prescribing physicians.

24 **Thirteenth Defense**

25 13. The product at issue was not in a defective condition or unreasonably dangerous  
26 at the time it left the control of the manufacturer or seller.

27 **Fourteenth Defense**

28 14. Bextra® was at all times material to the Complaint reasonably safe and

1 reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at  
 2 the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its  
 3 approved usages.

#### 4 **Fifteenth Defense**

5 15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as  
 6 the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable  
 7 standard of care.

#### 8 **Sixteenth Defense**

9 16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in  
 10 the Complaint, the same were caused by the unforeseeable alteration, change, improper handling,  
 11 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or  
 12 persons acting on its behalf after the product left the control of Defendants.

#### 13 **Seventeenth Defense**

14 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of  
 15 Defendants.

#### 16 **Eighteenth Defense**

17 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or  
 18 subsequent conditions unrelated to Bextra®.

#### 19 **Nineteenth Defense**

20 19. Plaintiff knew or should have known of any risk associated with Bextra®;  
 21 therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

#### 22 **Twentieth Defense**

23 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims  
 24 are preempted in accordance with the Supremacy Clause of the United States Constitution and by  
 25 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

#### 26 **Twenty-first Defense**

27 21. Plaintiff's claims are barred in whole or in part under the applicable state law  
 28 because the subject pharmaceutical product at issue was subject to and received pre-market

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1 approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

2 **Twenty-second Defense**

3 22. The manufacture, distribution and sale of the pharmaceutical product referred to  
4 in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,  
5 and Plaintiff's causes of action are preempted.

6 **Twenty-third Defense**

7 23. Plaintiff's claims are barred in whole or in part by the deference given to the  
8 primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical  
9 product at issue under applicable federal laws, regulations, and rules.

10 **Twenty-fourth Defense**

11 24. Plaintiff's claims are barred in whole or in part because there is no private right of  
12 action concerning matters regulated by the Food and Drug Administration under applicable  
13 federal laws, regulations, and rules.

14 **Twenty-fifth Defense**

15 25. Plaintiff's claims are barred in whole or in part because Defendants provided  
16 adequate "direction or warnings" as to the use of the subject pharmaceutical product within the  
17 meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

18 **Twenty-sixth Defense**

19 26. Plaintiff's claims are barred or limited to a product liability failure to warn claim  
20 because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement  
21 (Second) of Torts § 402A, Comment k.

22 **Twenty-seventh Defense**

23 27. Plaintiff's claims are barred in whole or in part because the subject  
24 pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning  
25 of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

26 **Twenty-eighth Defense**

27 28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of  
28 Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State of Ohio, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Ohio law, including, but not limited to, Minn. Stat. § 549.191 (2006).

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiff's punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States

1 Constitution.

2 **Thirty-seventh Defense**

3 37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if  
4 any, and labeling with respect to the subject pharmaceutical products were not false or  
5 misleading and, therefore, constitute protected commercial speech under the applicable  
6 provisions of the United States Constitution.

7 **Thirty-eighth Defense**

8 38. To the extent that Plaintiff seeks punitive damages for the conduct which  
9 allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by  
10 applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due  
11 process protections afforded by the United States Constitution, the excessive fines clause of the  
12 Eighth Amendment of the United States Constitution, the Commerce Clause of the United States  
13 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the  
14 Constitutions of the States of Minnesota and Ohio. Any law, statute, or other authority  
15 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially  
16 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient  
17 standards to guide and restrain the jury's discretion in determining whether to award punitive  
18 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate  
19 advance notice as to what conduct will result in punitive damages; (3) permits recovery of  
20 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or  
21 conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits  
22 recovery of punitive damages in an amount that is not both reasonable and proportionate to the  
23 amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5)  
24 permits jury consideration of net worth or other financial information relating to Defendants; (6)  
25 lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of  
26 any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review  
27 of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent,  
28 including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO*



1 Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North America,  
2 Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408  
3 (2003).

4 **Thirty-ninth Defense**

5 39. The methods, standards, and techniques utilized with respect to the manufacture,  
6 design, and marketing of Bextra®, if any, used in this case, included adequate warnings and  
7 instructions with respect to the product's use in the package insert and other literature, and  
8 conformed to the generally recognized, reasonably available, and reliable state of the knowledge  
9 at the time the product was marketed.

10 **Fortieth Defense**

11 40. The claims asserted in the Complaint are barred because Bextra® was designed,  
12 tested, manufactured and labeled in accordance with the state-of-the-art industry standards  
13 existing at the time of the sale.

14 **Forty-first Defense**

15 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon  
16 information and belief, such injuries and losses were caused by the actions of persons not having  
17 real or apparent authority to take said actions on behalf of Defendants and over whom  
18 Defendants had no control and for whom Defendants may not be held accountable.

19 **Forty-second Defense**

20 42. The claims asserted in the Complaint are barred, in whole or in part, because  
21 Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it  
22 was intended, and was distributed with adequate and sufficient warnings.

23 **Forty-third Defense**

24 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of  
25 laches, waiver, and/or estoppel.

26 **Forty-fourth Defense**

27 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of  
28 the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or

1 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were  
2 independent of or far removed from Defendants' conduct.

3 **Forty-fifth Defense**

4 45. The claims asserted in the Complaint are barred, in whole or in part, because  
5 Bextra® did not proximately cause injuries or damages to Plaintiff.

6 **Forty-sixth Defense**

7 46. The claims asserted in the Complaint are barred, in whole or in part, because  
8 Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

9 **Forty-seventh Defense**

10 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
11 manufacturing, labeling, packaging, and any advertising of the product complied with the  
12 applicable codes, standards and regulations established, adopted, promulgated or approved by  
13 any applicable regulatory body, including but not limited to the United States, any state, and any  
14 agency thereof.

15 **Forty-eighth Defense**

16 48. The claims must be dismissed because Plaintiff would have taken Bextra® even if  
17 the product labeling contained the information that Plaintiff contends should have been provided.

18 **Forty-ninth Defense**

19 49. The claims asserted in the Complaint are barred because the utility of Bextra®  
20 outweighed its risks.

21 **Fiftieth Defense**

22 50. Plaintiff's damages, if any, are barred or limited by the payments received from  
23 collateral sources.

24 **Fifty-first Defense**

25 51. Defendants' liability, if any, can only be determined after the percentages of  
26 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if  
27 any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants  
28 and each and every other person whose fault could have contributed to the alleged injuries and

1 damages, if any, of Plaintiff.

2 **Fifty-second Defense**

3 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in  
4 that the common law gives deference to discretionary actions by the United States Food and  
5 Drug Administration under the Federal Food, Drug, and Cosmetic Act.

6 **Fifty-third Defense**

7 53. The claims asserted in the Complaint are barred, in whole or in part, because  
8 Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug, &  
9 Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated there under, and  
10 Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to  
11 implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing  
12 regulations, and with the specific determinations by FDA specifying the language that should be  
13 used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by  
14 the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
15 United States.

16 **Fifty-fourth Defense**

17 54. Plaintiff's misrepresentation allegations are not stated with the degree of  
18 particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

19 **Fifty-fifth Defense**

20 55. Plaintiff's claims for punitive damages are barred, in whole or in part, by §  
21 2315.21 of the Ohio Revised Code and are subject to all provisions of the Ohio Revised Code.

22 **Fifty-sixth Defense**

23 56. Plaintiff's damages, if any, are barred or limited by the payments received from  
24 collateral sources and the provisions of the Ohio Revised Code.

25 **Fifty-seventh Defense**

26 57. Plaintiff's fraud-based claims, if any, are not stated with particularity as required  
27 by Ohio law.

28 **Fifty-eighth Defense**

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1 58. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable  
2 to Plaintiff and to nonparties as provided by the Ohio Revised Code.

3 **Fifty-ninth Defense**

4 59. One or more of Plaintiff's claims for damages are subject to statutory limits on  
5 certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiff  
6 beyond the limits set forth in the Ohio Revised Code.

7 **Sixtieth Defense**

8 60. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections  
9 throughout the Ohio Revised Code, bar or limit one or more of Plaintiff's claims, including the  
10 limits and restrictions on damages set forth herein.

11 **Sixty-first Defense**

12 61. Defendants reserve the right to supplement their assertion of defenses as they  
13 continue with their factual investigation of Plaintiff's claims.

14 **V.**

15 **JURY DEMAND**

16 Defendants hereby demand a trial by jury.

17 **VI.**

18 **PRAYER**

19 WHEREFORE, Defendants pray that Plaintiff takes nothing by this suit; that Defendants  
20 be discharged with their costs expended in this matter, and for such other and further relief to  
21 which Defendants may be justly entitled.

22 Dated: July 22, 2008.

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23 By \_\_\_\_\_/s/ \_\_\_\_\_

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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

THOMAS LAUER,  
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
G.D. SEARLE LLC and MONSANTO  
COMPANY,

Defendants.

) MDL Docket No. 1699  
)  
) CASE NO. 3:08-cv-02854-CRB  
)  
) **RULE 7.1 STATEMENT**  
)  
) **JURY DEMAND ENDORSED**  
) **HEREIN**

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Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. (“Pfizer”),  
 Pharmacia Corporation (“Pharmacia”), and G.D. Searle LLC (“Searle”) submit this their  
 Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.’s stock.
2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.
3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

Respectfully submitted,

Dated: July 22, 2008.

GORDON & REES LLP

By \_\_\_\_\_/s/ \_\_\_\_\_

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Dated: July 22, 2008

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